Gregg L. Weiner
Stephen S. Rabinowitz
Fried, Frank, Harris, Shriver
& Jacobson LLP
One New York Plaza
New York, NY 10004
(212) 859-4000

Attorneys for Plaintiff Keryx Biopharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.,

ECF CASE

Plaintiff,

07 Civ. 10376 (CSH)

- against -

DECLARATION OF GREGG L. WEINER IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

PANION & BF BIOTECH, INC.,

Defendant.	
	- X

Gregg L. Weiner declares the following pursuant to 28 U.S.C. §1746:

- 1. I am a member of the Bar of this Court and of the firm of Fried, Frank, Harris, Shriver & Jacobson LLP, counsel for plaintiff Keryx Biopharmaceuticals, Inc. ("Keryx") in this action. I make this declaration in support of Keryx's motion for a preliminary injunction. I have personal knowledge of the matters stated in this declaration, except as otherwise stated.
- 2. Attached as Exhibit A is a true copy of the Declaration of Michael S. Weiss, filed with the Court on November 19, 2007 in connection with Keryx's motion for a preliminary injunction and application for expedited discovery and adjudication of its claims in this action, together with the exhibits to Mr. Weiss' declaration. (Pursuant to the Court's November 19,

2007 order, Exhibit 1 to the Weiss Declaration is to be filed under seal.)

3. Attached as Exhibit B is a true copy of the Declaration of Gregg L. Weiner, filed with the Court on November 19, 2007 in connection with Keryx's motion for a preliminary injunction and application for expedited discovery and adjudication of its claims in this action, together with the exhibits to that declaration.

4. Upon information and belief, attached as Exhibit C is a true copy of the Summons With Notice filed yesterday, November 19, 2007 by Jack W. Chung on behalf of the defendant Panion & BF Biotech, Inc. against BioVectra DCL in the Supreme Court of the State of New York, County of Queens.

I, GREGG L. WEINER, hereby declare under penalty of perjury under the laws of the United States and the foregoing is true and correct.

Dated: November 20, 2007

559745

EXHIBIT A

Gregg L. Weiner
Stephen S. Rabinowitz
Fried, Frank, Harris, Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004-1980
(212) 859-8000
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.

07 Civ. 10376 (CSH)

Plaintiff,

DECLARATION OF MICHAEL S. WEISS

- against -

PANION & BF BIOTECH, INC.,

Defendant.

1. I am the Chairman and CEO of Keryx Biopharmaceuticals, Inc. ("Keryx"), a position I have held since December, 2002. I make this declaration in support of Keryx's application for expedited discovery and related relief in connection with Keryx's motion for a preliminary injunction and expedited adjudication of its claims in this action. I have knowledge of the matters stated in this declaration, based on my personal participation in and recollection of the events described below, my review of the relevant correspondence and consultation with responsible Keryx personnel.

2. Keryx is a publicly traded pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious conditions, including diabetes, cancer, and renal (kidney) disease.

Filed 11/26/2007

- 3. Under an exclusive patent license (the "License Agreement") from Panion & BF Biotech, Inc. ("Panion"), dated November 7, 2005, Keryx is developing a chemical compound, ferric citrate, as a pharmaceutical for treatment of hyperphosphatemia or phosphate retention, which is a common and serious complication of advanced renal disease. Under the License Agreement, Keryx's exclusive rights to develop and commercialize ferric citrate extend throughout most of the world, including the United States, Japan, and Canada, and include the right to grant sublicenses to third parties.
- Keryx has devoted substantial corporate resources and incurred substantial expenses in performing two categories of development work for ferric citrate. The first category includes work undertaken to generate information that is needed for successful commercialization of ferric citrate as a pharmaceutical, including (i) process improvements to find more cost-effective ways of manufacturing pharmaceutically-pure ferric citrate; (ii) developing the specifications and quality control tests for the Chemistry, Manufacturing and Controls ("CMC") submission that is required by the federal Food and Drug Administration (FDA); and (iii) improvements to the dosage form of the product to make it more acceptable to patients. These information-generating development activities do not result in Keryx being supplied with ferric citrate. BRI Pharmaceutical Research, Inc. ("BRI"), located in Vancouver, Canada, BioVectra DCL ("BioVectra"), located in Prince Edward Island, Canada, and the PharmPro Services division of Fluid Air, Inc.

Filed 11/26/2007

("PharmPro"), located in Aurora, IL, as contractors, are assisting Keryx with these development activities.

- Section 3.1 of the License Agreement expressly authorizes Keryx to 5. use Panion-owned technology ("Licensor Know-How") to "develop, have developed, make [and] have made" the licensed product. Attached as Exhibit 1 is a copy of the License Agreement. To the best of my knowledge, Panion has not accused Keryx of breaching the License Agreement by performing this first category of informationgenerating work.
- The second category concerns work that involves providing a supply of ferric citrate to Keryx, for use in (i) toxicology testing in animals, and (ii) clinical trials in humans to prove safety and efficacy. Section 7.7(b) of the License Agreement provides that during an Exclusive Supply Period (which has not yet expired), and subject to certain conditions, Keryx and its sublicensees shall obtain their supply of the Clinical Supplies of the Compound exclusively from Panion, subject to certain price competition provisions.
- On September 18, 2007, Keryx advised Panion that it was about to 7. grant an exclusive sublicense for Japan (the "Japanese Sublicense") to Japan Tobacco, Inc. and Torii Pharmaceutical Co. Ltd. (collectively, "Japan Tobacco") and requested Panion to sign a consent form for the comfort and assurance of the sublicensees (even though Panion's consent was not contractually required). Panion declined to sign the consent form, and the Japanese Sublicense was nevertheless executed, with effect from September 26, 2007, for an upfront licensing fee of \$12

million plus future milestone payments and royalties, collectively estimated to be worth \$100 million.

- 8. On September 22, 2007, after learning about the Japanese Sublicense, Panion for the first time accused Keryx of having breached the License Agreement by ordering certain supplies of ferric citrate from BioVectra in 2006.¹ On October 31, 2007, Panion's counsel, Albert Wai-Kit Chan, emailed to Keryx a notice contending that Keryx's orders in 2006 constituted "a material breach" of the License Agreement that "has not been cured for more than ninety days" and threatening to "take appropriate actions to nullify th[e] agreement." (A copy of the October 31, 2007 email is attached as Exhibit 2). Section 12.3 of the License Agreement permits termination for cause only if Keryx fails to cure a material breach within ninety days after Panion has given written notice of default. Panion has not retracted its false claim that the ninety-day cure period has expired or its threat to terminate the License Agreement.
- 9. On or about November 7, 8 and 9, 2007, Panion's counsel contacted Keryx's contractors, BRI, BioVectra and PharmPro, demanding that they cease the work they are performing for Keryx, on the grounds that they are using Panion-owned technology, and threatening to commence proceedings against them unless they agreed to do so. See letters from Jack Chung, Esq. to BRI (attached as Exhibit 3); letters from Jack Chung, Esq. to BioVectra (attached as Exhibit 4); letter from Jack Chung, Esq. to PharmPro, referring to earlier "demand letter" dated November

Keryx denies that it has breached the License Agreement and at the appropriate time will show that Panion knew about and acquiesced in the acts that Panion now denominates as a breach.

- 9, 2007 (attached as Exhibit 5). That work includes the information-gathering development work that Keryx is authorized under the License Agreement to do or have done, even if that were to require using Panion's "Licensor Know-How."
- 10. On November 12, 2007, counsel for Keryx wrote to Panion's counsel, explaining that Keryx believed it had not breached the License Agreement, giving an assurance that during the Exclusive Supply Period Keryx would submit future orders for clinical supplies of ferric citrate to Panion in accordance with Section 7.7(b) of the License Agreement, and asking Panion to confirm that this sufficed to cure the alleged breach or else to state what else was needed to cure. Keryx also asked Panion to cease and desist from threatening Keryx's contractors.
- 11. Panion did not reply to the November 12, 2007 letter, but instead repeated and escalated its threats and demands to BRI, BioVectra and PharmPro, (see Exhibits 3-5) and on November 15, 2007 filed a Summons with Notice in New York Supreme Court, Queens County, purporting to assert claims against BRI and seeking to enjoin BRI from continuing its contract work for Keryx.
- its sublicensee concerning the prosecution in Japan of the patent rights that Panion licensed to Keryx and that Keryx has in turn sublicensed to Japan Tobacco. Section 8.1.1 of the License Agreement provides that Panion shall "use reasonable efforts to prosecute the patent applications" that are included in the license and shall "regularly consult with Licensee and shall keep Licensee advised of the status of all patents and patent applications relating to the Patent Rights . . . " (See License Agreement, Exhibit 1 hereto). Japan Tobacco's patent counsel was initially permitted to meet

with Panion's Japanese patent counsel to discuss how to respond to a Notice of Office Action issued by the Japanese Patent Office, to which a response will be due on November 28, 2007 unless that deadline is extended. Panion has now instructed its Japanese patent counsel not to communicate with Japan Tobacco's counsel. (See Exhibit 2, email from A. Chan, Esq., dated October 31, 2007, stating that "Panion has instructed the Japanese associate not to communicate with any third party but Panion.") In addition, having agreed on October 24, 2007 to request a three-month extension of the deadline for responding to the Notice of Office Action, which Japanese counsel believes is important to procuring a patent in Japan, Panion switched course and informed Keryx that it would not seek the extension "based on the unresolved issues between Keryx and Panion." (See emails from A. Chan, Esq. dated October 24 and October 25, 2007, attached as Exhibit 6).

- Keryx will suffer severe and irreparable harm unless it can promptly present to the Court its motion for preliminary relief and unless the Court grants accelerated discovery and an accelerated schedule for resolving this controversy.
- A premature notice terminating the License Agreement -- and 14. purporting to cut off Keryx's opportunity to cure any alleged breach -- would cast a cloud over the Japanese Sublicense, causing severe and irreparable reputational injury to Keryx in the eyes not only of Japan Tobacco, but also of the wider Japanese pharmaceutical community. Further, a purported termination would gravely impair the ability of Japan Tobacco to commit the substantial sums necessary to perform the development work needed to obtain regulatory approval for ferric citrate in Japan. This would inevitably delay, and might entirely prevent, approval in Japan.

Filed 11/26/2007

- Panion's threats and actions against BRI, BioVectra and PharmPro 15. will likewise cause Keryx severe and irreparable reputational injury and hinder the information-gathering activities being performed under contract to Keryx, thereby delaying Keryx's developmental program.
- Delay in drug development will cause Keryx harm that is severe, 16. irreparable, and cannot be adequately compensated by money damages. Delayed approval and launch will shorten the period during which Keryx can sell its product under protection of its exclusive patent license, before it becomes exposed to generic competition. In addition, delay in launching the drug will cause Keryx to lose ground in the race to market against competing therapies that are being developed. Once lost, that lead time can never be recovered.
- Finally, successful prosecution of the Japanese patent application is 17. critical to commercial development under the Japanese Sublicense. Keryx urgently needs to present its motion for preliminary relief requiring Panion to cooperate with Keryx and its sublicensee in prosecuting that application, and to seek the three-month extension to which it previously agreed.
- In an attempt to avoid the need for immediate relief from the Court, I 18. sent an email yesterday to Panion's chairman proposing that the parties enter into a stipulation whereby (i) the time to cure any alleged breach would be extended until 20 business days after the Court had finally ruled whether a material breach in fact occurred, (ii) Keryx would give certain undertakings concerning sourcing of Clinical Supplies; (iii) Panion would not interfere with work performed by Keryx's contractors and would dismiss the action it filed against BRI, and (iv) Panion would

request an extension of the time for responding to the Japanese Patent Office. As of 10:00 a.m today, Panion has not indicated that it has any interest in entering into or discussing a stipulation.

I, MICHAEL S. WEISS, hereby declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Dated: November 19, 2007

Michael S. Weiss

EXHIBIT 1

Exhibit 1 to
the Declaration of Michael S. Weiss,
the License Agreement,
was previously served on Defendant and,
pursuant to the Court's order
dated November 19, 2007,
has been submitted for filing and
is to be filed under seal.

EXHIBIT 2

From: chank [chank@kitchanlaw.com]

Sent: Wednesday, October 31, 2007 10:52 AM

To: blevine@keryx.com

Cc: lgenovesi@keryx.com; chank; Cindy Chiang (PBF)

Subject: Dkt #1100-A

Dear Beth,

Further to your October 26, 2007 e-mail, please note the following:

Dr. Hsu and Ms. Marlene Hsu

Panion was unaware of Marlene Hsu or Dr. Chen Hsing Hsu's activities. Panion will investigate this matter.

Extension of Time

Regarding the extension of time for responding to the pending Japanese office action (Dkt #1092-PCT-JP), the Panion-Keryx office procedure clearly indicates that any extension of time should be avoided. A response to the Office Action is due November 28, 2007. Extensions are a judgment call. Panion has been and will be diligently pursing Panion's patents in Japan. This activity should not be interfered with nor threatened by any party. Panion has instructed the Japanese associate not to communicate with any third party but Panion.

Material Breach

The violation of the API clause is a material breach of the licensing agreement between Keryx and Panion. This material breach has not been cured for more than ninety days. See section 12.3 of the Licensing Agreement. API made by inappropriate specification may lead to clinical results which will ruin the Panion's valuable invention.

Unless we hear from Keryx immediately, we will take appropriate actions to nullify this agreement.

We look forward to hearing from you.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D. /ah Law Offices of Albert Wai-Kit Chan, PLLC World Plaza, Suite 604 141-07 20th Avenue Whitestone, NY 11357

Tel: (718) 799-1000 Fax: (718) 357-8615

E-mail: chank@kitchanlaw.com

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retransmission, dissemination or other use of, or taking any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer. Thank you for your cooperation.

EXHIBIT 3

LAW OFFICES OF

JACK W. CHUNG P.C.

401 BROADWAY, SUITE 2009

NEW YORK, NY 10013

U.S.A.

212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

VIA E-MAIL (dkwok@bripharm.com)
David Kwok, Ph.D.
President & CEO
BRI Biopharmaceutical Research Inc.
101 – 8898 Heather Street
Vancouver, BC
Canada V6P 3S8

November 7, 2007

Re: Unauthorized Manufacturing of Ferric Citrate Using Panion Technology

Dear Dr. Kwok:

This office acknowledges receipt of your letter by email dated November 6, 2007.

We have been informed that BRI has been using Panion's technology to facilitate the unauthorized production of four (4) different batches of API Ferric Citrate for one of Panion & BF Biotech Inc.'s licensees. Furthermore, your company has been using Panion's technology to perform quality and/or control analysis for these batches.

BRI is not allowed to disclose this Panion technology to any third party. Accordingly, we demand your company to (1) stop any and all ongoing activities IMMEDIATELY; (2) report any and all ongoing activities to Panion involving the use of Panion's technology to any third party; (3) make an affidavit that BRI has not used or disclosed Panion's technology to any third party.

Sincerely,

Jack W. Chung

JACK W. CHUNG P.C. 401 BROADWAY, SUITE 2009 NEW YORK, NY 10013 U.S.A.

> 212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

alde the chy

VIA E-MAIL (dkwok@bripharm.com)

David Kwok, Ph.D.
President & CEO
BRI Biopharmaceutical Research Inc.
101 – 8898 Heather Street
Vancouver, BC
Canada V6P 358

November 8, 2007

Re: Unauthorized Quality Control Testing of Ferric Citrate Involving Panion Technology

Dear Dr. Kwok:

Thank you for your prompt response dated November 8, 2007. We need the following information to clarify your position in this matter.

You did not make it clear on the current situation. Thus, we demand information on all current and ongoing Quality Control testing for Keryx or any third party in connection with Ferric Citrate using Panion Technology. Please provide us with documents and proof.

Additionally, we demand information with respect to, (1) the quantity of Quality Control tests your company has done for Keryx or any third party in connection with Ferric Citrate; (2) the timeframe of when these Quality Control tests were done; and, (3) the inventory log for these tests.

You stated that "[w]ith Panion's knowledge, BRI is currently engaged by Keryx to perform QC testing on ferric citrate materials provided by Keryx." You did not make it clear about this "Panion's knowledge." We demand documents and proof of "Panion's knowledge."

You further stated that "BRI's role as CRO in providing analytical chemistry service to Keryx at Panion's request." Again, we demand documents and proof of "Panion's request."

This is a very urgent matter. We hope that you will respond to my requests today so that we may resolve this matter in a professional manner.

Sincerely,

Jack W. Chung

Case 1:07-cv-10376-CSH

Document 14-5

Filed 11/26/2007

Page 4 of 4

LAW OFFICES OF

JACK W. CHUNG P.C.

401 BROADWAY, SUITE 2009

NEW.YORK, NY 10013

U.S.A.

212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

VIA E-MAIL (dkwok@bripharm.com)

David Kwok, Ph.D.
President & CEO
BRI Biopharmaceutical Research Inc.
101 – 8898 Heather Street
Vancouver, BC
Canada V6P 3S8

November 14, 2007

Re: Final Notice From Panion

Dear Dr. Kwok:

You have not responded to our communication of November 12, 2007 regarding the affidavit. We tried every attempt to resolve these matters in an amicable manner. However, you have not signed and returned the affidavit to us. Thus, you have left us with no choice but to take the appropriate actions as necessary.

This letter is to notify you that we will prepare legal papers to initiate a lawsuit against your company. However, you are given one more chance to resolve this matter amicably. If we do not receive the executed affidavit by Friday, November 16, 2007, Panlon will sue.

Please be guarded accordingly.

Sincerely,

Jack W,/Chung

cc: Clara Faan (via e-mail: cfaan@bripharm.com)

EXHIBIT 4

Filed 11/26/2007

Page 2 of 4

401 BROADWAY, SUITE 2009 NEW YORK, NY 10013 U.S.A.

> 212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

November 9, 2007

VIA E-MAIL (rkeefe@biovectra.com; sball@biovectra.com) AND FEDEX

Mr. Ron Keefe President Bio Vectra DCL 16 McCarville Street Charlottetown, Prince Edward Island Canada, C1E 2A6

Mr. Stephen Ball Bio Vectra DCL 16 McCarville Street Charlottetown, Prince Edward Island Canada, C1E 2A6

Re: Unauthorized Uses of Panion's Technologies in connection with Ferric Citrate

Dear Mr. Keefe, Mr. Ball:

Our firm represents Panion & BF Biotech Inc., (hereinwith, "Panion").

It has been brought to our attention that your company has been using the Panion technologies to manufacture Active Pharmaceutical Ingredient of Ferric Citrate. This use has not been authorized by Panion. We therefore demand your company:

- 1. to stop the manufacturing process immediately; and
- 2. provide to us a detailed breakdown of how many batches made.

This is a very serious matter and the technologies are of great value to our client. We look forward to hearing from you immediately. If we do not hear from you by November 13, 2007, we will take appropriate actions without further notice.

Please guard yourself accordingly.

Sincerely,

Cc: Dr. David Kwok
BRI Biopharmaceutical Research Inc.
101 – 8898 Heather Street
Vancouver, BC

Canada V6P 3S8

Jack W. Chung

JACK W. CHUNG P.C.

401 BROADWAY, SUITE 2009 NEW YORK, NY 10013 U.S.A.

> 212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

November 13, 2007

VIA E-MAIL (rkeefe@biovectra.com; sball@biovectra.com)

Mr. Ron Keefe
President
Bio Vectra DCL
16 McCarville Street
Charlottetown, Prince Edward Island
Canada, C1E 2A6

Mr. Stephen Ball Bio Vectra DCL 16 McCarville Street Charlottetown, Prince Edward Island Canada, C1E 2A6

Re: Notice to Stop Using Panion's Technologies

Dear Mr. Keefe, Mr. Ball:

I have not heard from you regarding the demand letter I sent you on November 9, 2007. Notice is hereby given to you that BioVectra must stop using Panion's technologies immediately. If BioVectra fails to do so, BioVectra will be liable for all the damages incurred to Panion.

If I do not hear from you today, I will have to advise my client to take appropriate actions. It will be in your best interest to resolve this matter as soon as possible.

Cc: Dr. David Kwok

BRI Biopharmaceutical Research Inc.

101 - 8898 Heather Street

Vancouver, BC

Canada V6P 3S8

Sincerely,

Jack W. Chung

LAW OFFICES OF

JACK W. CHUNG P.C.

401 BROADWAY, SUITE 2009 NEW YORK, NY 10013 U.S.A.

212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

November 15, 2007

VIA E-MAIL (vdeighan@biovectra.com)

Valana Deighan
Associate General Counsel
Diagnostic Chemicals Limited
16 McCarville Street
Charlottetown, PEI
C1E 2A6
Canada

Re: Second Notice to Stop Using Panion's Technology

Dear Ms. Deighan:

You have not responded to our letter dated November 13, 2007.

Notice is hereby given to you again to stop using Panion's technologies immediately. If BioVectra fails to do so, legal action will be initiated against BioVectra for all the damages incurred to Panion.

Demand is hereby made once again to provide us with a detailed breakdown of how many batches were made.

Sincerely,

Jack W. Chung

cc: Ron Keefe (via e-mail: rkeefe@biovectra.com)

Dale Zajicek (via e-mail: dzajicek@biovectra.com)

Dr. David Kwok (via e-mail: dkwok@bripharm.com)

BRI Biopharmaceutical Research Inc.

101 - 8898 Heather Street

Vancouver, BC

Canada V6P 3S8

EXHIBIT 5

LAW OFFICES OF

JACK W. CHUNG P.C.

401 BROADWAY, SUITE 2009 NEW YORK, NY 10013 U.S.A.

212-334-7118 FAX 212-334-6408 JACKCHUNGLAW@GMAIL.COM

November 13, 2007

VIA E-MAIL (mpb@fluidairinc.com)

Mr. Martin P. Bender
President
PharmPro – Processing Services of Fluid Air Inc.
2550 White Oak Circle
Aurora, IL 60504-9678

Re: Notice to Stop Using Panion's Technologies

Dear Mr. Bender:

I have not heard from you regarding the demand letter I sent you on November 9, 2007 and November 12, 2007. Notice is hereby given to you that PharmPro must stop using Panion's technologies immediately. If PharmPro fails to do so, PharmPro will be liable for all the damages incurred to Panion.

If I do not hear from you today, I will have to advise my client to take appropriate actions. It will be in your best interest to resolve this matter as soon as possible.

Sincerely,

Cc: Dr. David Kwok
BRI Biopharmaceutical
Research Inc.
101 – 8898 Heather Street
Vancouver, BC
Canada V6P 3S8

Jack W. Chung

EXHIBIT 6

From: chank [mailto:chank@kitchanlaw.com] Sent: Thursday, October 25, 2007 2:40 AM To: Genovesi, Lina [lgenovesi@keryx.com]

Cc: Levine, Beth [blevine@keryx.com]; Cindy Chiang (PBF); Weiss, Michael S. [msw@keryx.com]; chank

Subject: RE: Our Dkt #1092-PCT-JP

Dear Lina,

Contrary to our below email, we might not be able to carry out your recommendation based on the unresolved issues between Keryx and Panion.

Please acknowledge receipt of this e-mail via e-mail.

Sincerely,

Albert Wai-Kit Chan Law Offices of Albert Wai-Kit Chan, PLLC World Plaza, Suite 604 141-07 20th Avenue Whitestone, NY 11357 Tel: (718) 799-1000

Fax: (718) 357-8615

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From: |genovesi@keryx.com [mailto:|genovesi@keryx.com]

Sent: Wed 10/24/2007 2:21 PM

To: chank

Subject: RE: Our Dkt #1092-PCT-JP; your File: X1G-0774

received

Lina Genovesi, PhD, JD
Director of Legal Affairs
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue, 20th Floor
New York, New York 10022
Phone: (212) 531-5968

Fax: (212) 531-5961

lgenovesi@keryx.com http://www.keryx.com

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----Original Message----

From: chank [mailto:chank@kitchanlaw.com]
Sent: Wednesday, October 24, 2007 2:19 PM
To: Genovesi, Lina [lgenovesi@keryx.com]

Cc: chank; Levine, Beth [blevine@keryx.com]; Cindy Chiang (PBF); michaelchiang@pbf.com.tw

Subject: RE: Our Dkt #1092-PCT-JP; your File: X1G-0774

Dear Lina,

Further to your e-mail earlier today, we will proceed as instructed and request a three month extension of time.

If you have any questions, feel free to contact us.

Please acknowledge receipt of this e-mail.

Sincerely,

Albert Wai-Kit Chan, Ph.D. /ah Law Offices of Albert Wai-Kit Chan, PLLC World Plaza, Suite 604 141-07 20th Avenue Whitestone, NY 11357

Tel: (718) 799-1000 Fax: (718) 357-8615

E-mail: chank@kitchanlaw.com

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----Original Message----

From: lgenovesi@keryx.com [mailto:lgenovesi@keryx.com]

Sent: Wednesday, October 24, 2007 9:30 AM

To: chank

Cc: blevine@keryx.com

Subject: FW: Our Dkt #1092-PCT-JP; your File: X1G-0774

Hi:

Please the strategy set forth below by JT. Please request a three months extension of time to allow for a response to be formulated.

Please confirm request of the extension and provide me with a copy.

Regards,

Lina

Lina Genovesi, PhD, JD
Director of Legal Affairs
Keryx Biopharmaceuticals, Inc.
750 Lexington Avenue, 20th Floor
New York, New York 10022

Phone: (212) 531-5968 Fax: (212) 531-5961

Igenovesi@keryx.com http://www.keryx.com

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EXHIBIT B

Gregg L. Weiner Stephen S. Rabinowitz Fried, Frank, Harris, Shriver & Jacobson LLP One New York Plaza New York, NY 10004 (212) 859-4000

Attorneys for Plaintiff Keryx Biopharmaceuticals, Inc.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff.

- against -

07 Civ. 10376 (CSH)

PANION & BF BIOTECH, INC.,

DECLARATION OF GREGG L. WEINER

Defendant.

Gregg L. Weiner declares the following pursuant to 28 U.S.C. §1746:

- 1. I am a member of the Bar of this Court and of the firm of Fried, Frank, Harris, Shriver & Jacobson LLP, counsel for plaintiff Keryx Biopharmaceuticals, Inc. ("Keryx") in this action. I make this declaration in support of Keryx's application for expedited discovery and related relief in connection with Keryx's motion for a preliminary injunction and application for expedited discovery and adjudication of its claims in this action. I have personal knowledge of the matters stated in this declaration, except as otherwise stated.
- 2. Attached as Exhibit 1 is a true copy of the Complaint filed in this action last Friday, November 16, 2007.
- 3. Attached as Exhibit 2 is a true copy of the letter dated November 12, 2007 from Stephen S. Rabinowitz, one of my partners, to Albert Wai-Kit Chan, counsel for defendant

Panion & BF Biotech, Inc.

4. No response to the letter annexed as Exhibit 2 has been received to date.

5. Attached as Exhibit 3 is a true copy of the email dated November 16, 2007 from

Gregg L. Weiner to Albert Wai-Kit Chan and Jack W. Chung (another attorney for defendant

Panion & BF Biotech, Inc.), attaching a letter I sent Mr. Chung and Dr. Chan on that date,

advising them of Keryx's application and providing a copy of the Summons and Complaint in

this action.

Upon information and belief, attached as Exhibit 4 is a true copy of the Summons

With Notice filed last Thursday, November 15, 2007 by Mr. Chung on behalf of the defendant

Panion & BF Biotech, Inc. against BRI Biopharmaceutical Research, Inc. in the Supreme Court

of the State of New York, County of Queens.

7. Upon information and belief, Exhibit 1 to the Declaration of Michael Weiss, a License

Agreement dated November 7, 2007 between Keryx Biopharmaceuticals, Inc. and Panion & BF

Biotech, Inc., contains confidential and commercially sensitive information that must be filed

under seal. The License Agreement is a valuable commercial contract, and Exhibit 1 contains

terms and conditions that are confidential and that should not be made available to Keryx's

competitors. Accordingly, Keryx respectfully requests that that Exhibit be filed under seal.

8. No prior request for the relief sought herein has been made in this or any other court.

I. GREGG L. WEINER, hereby declare under penalty of perjury under the laws of the

United States and the foregoing is true and correct.

Dated: November 19, 2007

559614

07 CV 10376

Gregg L. Weiner Stephen S. Rabinowitz Fried, Frank, Harris, Shriver & Jacobson LLP One New York Plaza New York, New York 10004-1980 (212) 859-8000 Attorneys for Plaintiff

UNITED STATES DISTRICT CO FOR THE SOUTHERN DISTRIC			The same
KERYX BIOPHARMACEUTICA	LS, INC.	x : \	07 NOV 18 2001
	Plaintiff,	:	U.S.D. SHIERS
- against -		:	COMPLAINT
PANION & BF BIOTECH, INC.,		:	
	Defendant.	: v	

Plaintiff Keryx Pharmaceuticals, Inc. ("Keryx"), by its attorneys, for its Complaint in this action, alleges as follows:

NATURE OF ACTION

1. This is an action for declaratory and injunctive relief and damages arising from the threatened termination of a license agreement under which defendant Panion & BF Biotech, Inc. ("Panion") granted Keryx exclusive rights to develop and commercialize a licensed pharmaceutical product for treatment of kidney disease. Panion's asserted basis for terminating the license agreement is incorrect. Moreover, in conjunction with its improper termination threats, Panion has breached the license agreement by attempting to prevent Keryx from developing the licensed product and has tortiously interfered with Keryx's ongoing contractual relations with third parties

who are assisting Keryx in developing the licensed product. Panion's actions threaten to cause Keryx irreparable harm.

PARTIES AND JURISDICTION

- 2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with its principal place of business at 750 Lexington Ave., 20th Floor, New York, NY 10022.
- 3. Upon information and belief, Panion is a corporation organized and existing under the laws of Taiwan, having an office in Queens County, New York and its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.
- 4. This action arises under the common law of the State of New York and the Declaratory Judgments Act, 28 U.S.C. §§ 2201 et seq.
- 5. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(a). The parties are of diverse citizenship, and the amount in controversy exceeds the sum or value of seventy-five thousand dollars (\$75,000), exclusive of interest and costs.
 - 6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a).

BACKGROUND

7. Keryx is a pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious and life-threatening diseases, including diabetes, cancer, and renal (kidney) disease.

The License Agreement

- 8. Panion is the owner or exclusive licensee of certain patents and patent applications, including U.S. Patent No. 5,7753,706, issued May 19, 1998, for an invention entitled "Methods For Treating Renal Failure" (the "Hsu Patent"). The Hsu Patent describes and claims a method of controlling phosphate retention in patients suffering from elevated phosphate levels by administering a therapeutically effective amount of ferric citrate. Phosphate retention leading to elevated phosphate levels is a common and serious complication of advanced renal disease.
- 9. Keryx and Panion are parties to a license agreement, dated November 7, 2005 (the "License Agreement") whereby Panion (Licensor) granted to Keryx (Licensee) an exclusive license under the Hsu Patent, its corresponding foreign counterparts, and other Panion-owned or Panion-controlled patents and patent applications, to develop and commercialize ferric citrate and pharmaceutical products containing ferric citrate as an active ingredient (collectively, the "Product") throughout most of the world, including but not limited to the United States, Canada and Japan, for treatment of renal disease.
 - 10. Section 3.1 of the License Agreement provides:
 - Grant. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive license, in the Territory, with the right to sublicense, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product in the Territory under the Licensor Know-How, and the Patent Rights for all Indications in the Field.
- 11. As defined in Section 1.13 of the License Agreement, the term "Licensor Know-How" includes:

discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise, in each case, which as of the Effective Date and during the term of this Agreement are necessary or useful to Licensee in connection with the development, registration, manufacture, marketing, use or sale of a Product.

12. Section 7.7 of the Agreement provides, in part:

Both parties agree to work in good faith to fully collaborate to review and administer the manufacturing program for the Compound and to resolve any technical issues both immediately after the Effective Date and at least annually thereafter during the Exclusive Supply Period as defined below.

For the period commencing on the Effective Date and continuing for three (3) years following Registration in the United States (the "Exclusive Supply Period"), Licensee (and its Sublicensees) shall obtain their supply of the Clinical Supplies and of the Compound exclusively from Licensor. In consideration for such supply, Licensee shall provide compensation to Licensor at fifteen percent (15%) over Licensor's manufacturing and procurement cost. Notwithstanding the preceding two sentences, decisions and actions related to pharmaceutical development and manufacturing of the Clinical Supplies are subject to joint review and approval. During the Exclusive Supply Period, Licensee shall be entitled to engage an alternative supplier of Clinical Supplies of the Compound provided that (i) Licensee has demonstrated to Licensor that the Clinical Supplies or the Compound subject to this Section 7.7(b) can be made available to Licensee by an alternative third-party supplier at a price that is more than 25% below what Licensor charges Licensee in accordance with this Section 7.7(b); and (ii) Licensor within sixty (60) days thereafter fails to meet the price offered by such alternative supplier.

13. After entering into the License Agreement, Keryx and Panion began discussing the development of improved processes and specifications for manufacturing, at commercially reasonable cost, Active Pharmaceutical Ingredient

("API") containing pharmaceutical-grade ferric citrate suitable for treatment of human patients suffering from advanced renal disease. A supply of API is indispensable for performing the preclinical testing and clinical trials that are needed to obtain regulatory approval from the Federal Food and Drug Administration ("FDA") and its foreign counterparts to commercialize pharmaceutical agents containing ferric citrate.

Panion's Acquiescence in Keryx's Orders of API

14. On July 26, 2006, Keryx sent an email to the President of Panion detailing an urgent need for 100kg of API to be sent under the conditions of the contract to begin critical path toxicology studies. Instead of responding in an urgent manner in spite of Keryx's repeated requests to supply quantities as low as 5 kg immediately so it could begin those studies, Panion introduced Keryx to its previous contractor, BRI Biopharmaceutical Research Inc. ("BRI"), located in Vancouver, Canada, for the purposes of organizing supply but then declined to participate in any planning, saying that it just wanted to be kept informed. Keryx kept Panion informed of its development program by emails and progress reports, and invited Panion to attend meetings with BRI, which Panion declined on the grounds that "Panion is a small company with limited budget and resources."

- 15. BRI introduced Keryx to BioVectra DCL ("BioVectra"), located in Prince Edward Island, Canada, and through BioVectra to a subcontractor, the PharmPro Services division of Fluid Air, Inc., ("PharmPro"), located in Aurora, IL. Working with BRI, BioVectra and PharmPro, Keryx has incurred significant expenditures and devoted substantial corporate resources to the development of specifications and manufacturing processes for API. Not until September 1, 2006, did Panion respond definitively that it had "checked the inventory and found out we don't have any quantity in stock."
- 16. On September 5, 2006, Keryx placed a purchase order with BioVectra for the manufacture of 400 kg of API, in 3 lots, under a quotation that Panion had requested Keryx to obtain and that had been emailed to Keryx, with a copy to Panion, on August 24, 2006. Despite its awareness of the impending order for production, Panion did not object to Keryx or offer to participate in any active way.
- order for API to cover any needs that Panion might have. Without objecting to Keryx's order or offering to take over the work of coordinating the production, Panion responded that it had sufficient API for its own purposes. After receiving Panion's response, Keryx ordered a fourth batch of API from BioVectra. Panion continued to be copied on emails periodically over the coming month and a half until production began, and then over the subsequent two months on discussions of changes in specifications and controls. At no time did it raise any objection to the fact that Keryx and BRI were working together to coordinate the production or offer

to participate in any active way. The four batches of API have been manufactured and title has passed to Keryx.

- 18. In February, 2007, after the production and formal release of the product for use, Keryx and Panion exchanged correspondence and finally a formal letter of understanding regarding regulatory reporting of the results of the production. At no time did Panion object to the fact that Keryx had organized the production and paid for it directly.
- has contracted and borne the entire expense for additional development work by BRI, BioVectra and PharmPro aimed at improving the efficiency (i.e., lowering the cost and increasing the yield) of producing API and assuring its stability. The continuing development work will not result in Keryx being supplied with additional API over and above the four lots that Keryx previously ordered. Keryx has now made a substantial investment in lowering the cost of manufacturing which is a critical component of commercializing ferric citrate (i.e., the development of a commercially feasible, cost-effective process for manufacturing pharmaceutically pure API suitable for clinical trials and commercial sale).

The Japanese Sublicense

20. On September 26, 2007 Keryx concluded an agreement (the "Sublicense") with Japan Tobacco, Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii") by which Keryx granted to JT and Torii an exclusive sublicense under the License Agreement to develop and commercialize ferric citrate in Japan, in exchange for an initial licensing fee of \$12 million plus future milestone and royalty payments.

Under the License Agreement, Panion is not entitled to share in the initial licensing fee or milestone payments.

Panion's Threatened Termination and Interference With Licensed Activities

- 21. On October 31, 2007 Panion's counsel sent Keryx an email contending that Keryx's purchases of API, under contracts entered into a year earlier, constituted a "material breach" of the Licensing Agreement that "has not been cured for more than ninety days" and threatening to take "appropriate actions to nullify the agreement." The License Agreement gives Panion (Licensor) a right to terminate for cause "upon or after the breach of any material provision . . . by Licensee if such breach is not cured within ninety (90) days after Licensor gives Licensee written notice thereof" No prior written notice of any alleged breach of the Licensing Agreement had been given to Keryx before October 31, 2007.
- 22. On or about November 8 and 9, 2007, Panion accused BRI, BioVectra and PharmPro of making improper use of Panion-owned technology and threatened to commence legal action against them unless they discontinued their contractual activities for Keryx.
- 23. On November 12, 2007, Keryx's counsel wrote to Panion's counsel pointing out that Panion had acquiesced in Keryx's prior purchases of API, stating that Keryx had no pending unfilled orders for supply of API, agreeing that Keryx would submit future purchase orders for supply of API to Panion in accordance with Section 7.7 of the License Agreement, and demanding that Panion cease and desist from threatening Keryx's contractors and that Panion retract the demands and allegations it had issued to them.

- 24. On November 13, 14 and 15, 2007, Panion's counsel again contacted PharmPro, BRI and BioVectra, respectively, again threatening that Panion would commence legal action unless they discontinued their contractual activities for Keryx.
- 25. On November 15, 2007, Panion filed a Summons with Notice in Queens County, New York asserting claims against BRI.

FIRST CAUSE OF ACTION (Breach of contract)

- 26. Paragraphs 1-25, above, are realleged and incorporated by reference as if set forth in full.
- 27. Under the License Agreement, Panion has authorized Keryx to use Panion-owned technology to "develop [and] have developed" API containing pharmaceutical-grade ferric citrate.
- 28. The threats and demands issued by Panion against BRI, BioVectra and PharmPro constitute a breach of Keryx's rights under the License Agreement to develop API.
- 29. Panion's conduct, unless enjoined, will cause Keryx irreparable harm for which it has no adequate remedy at law.

<u>SECOND CAUSE OF ACTION</u> (Tortious interference with contractual relations)

- 30. Paragraphs 1-29, above, are realleged and incorporated by reference as if set forth in full.
- 31. By demanding that BRI, BioVectra and PharmPro cease the development activities they are performing under contract to Keryx, Panion has tortiously interfered with the ongoing contractual relationship between Keryx and

BRI, BioVectra and PharmPro. Panion has made these demands knowing that they are contrary to the rights granted Keryx under the License Agreement and for the purpose of harming Keryx.

- 32. Unless enjoined, Panion will continue to interfere with Keryx's contracts with BRI, BioVectra and PharmPro.
- 33. Panion's conduct threatens Keryx with irreparable harm for which it has no adequate remedy at law.

THIRD CAUSE OF ACTION

(Declaratory judgment that Keryx has not breached the License Agreement)

- 34. Paragraphs 1-33, above, are realleged and incorporated by reference as if set forth in full.
- 35. Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro did not breach the License Agreement, among other reasons, because Panion acquiesced in and consented to those purchases.
- 36. Panion is estopped from contending that Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro constitute a breach of the License Agreement.
- 37. Moreover, any alleged breach by virtue of Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro did not materially breach the License Agreement.
- 38. A ripe, justiciable controversy exists between Panion and Keryx concerning whether Keryx has breached the Agreement by purchasing four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro.

FOURTH CAUSE OF ACTION (Anticipatory breach)

- 39. Paragraphs 1-38, above, are realleged and incorporated by reference as if set forth in full.
- 40. Section 12.3.1. of the License Agreement prohibits Panion from terminating the License Agreement for a material breach unless and until Keryx has failed to cure the breach within ninety (90) days after Panion has given Keryx written notice thereof.
- 41. In its initial notice dated October 31, 2007, Panion stated that Keryx's alleged material breach "has not been cured for more than ninety days" and threatened to take "actions to nullify th[e] agreement." Panion thereby breached the termination clause of the License Agreement by failing to give Keryx ninety days after notice to cure the alleged breach.
- 42. Panion is not entitled to terminate the License Agreement and its threat to do so breaches the express provisions thereof.
- 43. Panion's conduct threatens Keryx with irreparable harm for which it has no adequate remedy at law.

FIFTH CAUSE OF ACTION (Breach of contract)

- 44. Paragraphs 1-43, above, are realleged and incorporated by reference as if set forth in full.
 - 45. Section 8.1.1 of the License Agreement provides:

Licensor shall use reasonable efforts to prosecute the patent applications included in the Patent Rights . . . Licensor shall regularly consult with Licensee and shall keep Licensee advised of the status of all patent

applications and patents relating to the Patent Rights by providing Licensee with copies of such patent applications and patents and copies of all patent office correspondence relating thereto including any office actions received by Licensor and responses or other papers filed by Licensor. Licensor specifically agrees to provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Licensor any proposed response thereto. Licensor further agrees to provide Licensee with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult on all proposed responses to patent office correspondence relating to such patent applications and patents.

- 46. Keryx has repeatedly requested Panion to provide a comprehensive docket report on the Patent Rights licensed to Keryx under the License Agreement. Panion has neither provided the requested docket report, nor provided any explanation for its failure to comply with these requests.
- 47. On or about August 28, 2007, the Japanese Patent Office issued a Notice of Office Action concerning the Japanese counterpart of the Hsu Patent.
- 48. Panion initially permitted its Japanese patent counsel to collaborate with the patent counsel of Japan Tobacco, Keryx's sublicensee, in evaluating the Notice of Office Action and determining how to prepare a response.
- 49. On information and belief, it was agreed at the meeting between Panion's and Japan Tobacco's patent counsel that a 3-month extension should be sought so that Japan Tobacco could undertake a comprehensive search to identify and analyze published articles that support the patentability of the claimed subject matter.
- 50. On October 24, 2007, Panion's counsel notified Keryx that Panion would request a 3-month extension. The very next day, October 25, 2007, Panion's counsel sent Keryx a further email in which Panion refused to seek the extension

"based on the unresolved issues between Keryx and Panion." Panion also instructed its Japanese patent counsel to stop interacting with the patent counsel of Japan Tobacco.

- 51. Panion has breached the License Agreement by failing to consult in good faith with Keryx concerning prosecution of the licensed patent applications and by failing to keep Keryx informed of the status of the licensed patents and patent applications.
 - 52. Panion's conduct has damaged Keryx.WHEREFORE, Keryx demands judgment as follows:
 - 1. Declaring that:
 - a) Keryx is not in breach of the License Agreement;
 - b) the alleged breach concerning orders for supply of API is not material;
 - c) Keryx has until January 30, 2008 to cure any alleged breach concerning orders for supply of API; and
 - any notice by Panion purporting to terminate the License
 Agreement is null and void;
 - 2. Preliminarily and permanently enjoining:
 - a) Panion from issuing a notice to terminate the License

 Agreement before Keryx's time to cure any alleged

 breach has expired; and

- b) Panion from taking any action to interfere with Keryx's rights under the License Agreement, including its right to contract with third parties to develop the Product;
- Directing Panion to pay damages to Keryx in an amount to be determined at trial, with interest thereon;
- 4. Awarding Keryx punitive damages on its claim for tortious interference;
- 5. Awarding Keryx its costs and disbursements (including expert and attorneys' fees incurred in this action); and
- 6. Awarding Keryx such other and further relief as the Court may deem just and proper.

Dated: New York, New York November 16, 2007

FRIED, FRANK, HARRIS, SHRIVER &

JACOBSON LLP

By: Grace I

Stephen S. Rabinowitz

(Members of the Firm)

One New York Plaza New York, NY 10004-1980

(212) 859-8000

Attorneys for Plaintiff

Keryx Biopharmaceuticals, Inc.

EXHIBIT 2

Fried, Frank, Harris, Shriver & Jacobson LLP

One New York Plaza New York, New York 10004-1980 Tel: +1.212.859.8000 Fax: +1.212.859.4000 www.friedfrank.com



Direct Line: 212.859.8973 Fax: (212) 859-4000 srabinowitz@friedfrank.com

November 12, 2007

BY EMAIL AND FIRST CLASS MAIL

Albert Wai-Kit Chan, Ph.D., Esq. Law Offices of Albert Wai-Kit Chan PLLC World Plaza, Suite 604 141-07 20th Avenue Whitestone, NY 11357

Dear Dr. Chan:

This office represents Keryx Biopharmaceuticals, Inc. ("Keryx"). We write concerning the dispute that has arisen between Keryx and your client, Panion & BF Biotech, Inc. ("Panion") and in particular in response to your emails to Beth Levine of October 31 and November 5, 2007, alleging that Keryx is in material breach of the Panion-Keryx License Agreement and threatening to terminate that agreement. We also write concerning the letters sent by Jack Chung Esq., acting for Panion, on or about November 8 and 9, 2007, by which Panion has accused BRI Biopharmaceutical Research Inc. ("BRI") and BioVectra DCL ("BioVectra") of improperly using Panion-owned technology to produce Active Pharmaceutical Ingredient ("API") for Keryx, and by which Panion has sought to obtain from BRI and BioVectra documents containing trade secrets owned by Keryx.

Keryx rejects any claim that it has breached the Panion-Keryx License Agreement or acted improperly in any way. On the contrary, it is Panion that has contravened the letter and the spirit of the License Agreement, including by its unfounded and contrived claims of material breach against Keryx. Such claims - though frivolous - are potentially quite damaging to Keryx, as is Panion's attempt to interfere with the contractual relations between Keryx and its contractors, and to obtain Keryx's trade secrets. We expect that Keryx's responses to the specific issues you have raised will satisfactorily resolve these matters so that Keryx and Panion can focus on the development of Zerenex to their mutual benefit.

Sourcing of API from BRI/BioVectra 1.

Kervx rejects any allegation that it has breached Section 7.7(b) of the License Agreement by obtaining API from BRI/BioVectra. On the contrary, Keryx has at all times acted with

Albert Wai-Kit Chan, Ph.D., Esq.

November 12, 2007 Page 2

Panion's knowledge and acquiescence in working with these contractors to obtain API.

It was Panion itself that directed Keryx to collaborate with BRI, and as early as August 14, 2005 Panion was made aware of pending production plans at BRI and BioVectra for Keryx. Moreover, Keryx's direct contacts with BRI and BioVectra were necessitated by Panion's professed inability to supply Keryx with API, even in quantities as small as 5 kg. Indeed, when Keryx asked Panion to participate in an on-site meeting with BRI to discuss the API production, Panion declined, citing its "small" size and "limited" resources. Once Keryx's preparations for the production by BRI/BioVectra were complete, Keryx expressly offered to order additional API material for Panion's needs if desired, in order to save Panion the trouble of procuring additional API. Panion declined the offer, and at no time in that interaction suggested that Keryx was acting improperly in ordering API from BRI/BioVectra, although Panion had advance notice of the order and a clear opportunity to voice its objection, if it had any. At the conclusion of the production, Panion was fully aware that BioVectra had produced API for Keryx, and indeed asked Keryx to provide details of the specifications developed during those production activities by BRI and Keryx - at Keryx's substantial expense - so that Panion could include those specifications in its updated DMF. Even in the several formal interchanges regarding the specifications, Panion raised no objection about the production at BioVectra or the supporting analytical work at BRI.

In other words, Panion was fully aware of Keryx's dealings with BioVectra and BRI, to which Panion made no objection at the time and from which Panion benefited. Accordingly, Panion's belated allegation - 6 months after the fact - that those dealings purportedly constituted a "material breach" of the License Agreement is unjustified and without basis. Moreover, Panion's assertion, in your email dated October 31, 2007, that this alleged material breach "has not been cured for more than ninety days" is transparently frivolous. Section 12.3.1(a) of the License Agreement expressly gives Keryx the right to cure any breach "within ninety (90) days after Licensor gives Licensee written notice thereof." Since written notice of the alleged breach was only given (by email with subsequent confirmation by first class mail) on October 31, 2007, it is clear that the 90-day cure period had not then even commenced, let alone expired. Panion's statement to the contrary, with its accompanying threat to terminate the License Agreement, is false and in bad faith, and itself constitutes a breach of the License Agreement.

Keryx has already provided to Panion, in both hard copy and electronic format, the batch records for all four lots of API that Keryx obtained from BRI/BioVectra. By email dated September 17, 2007, Panion expressly acknowledged that it had received these batch records. Please note that Keryx has not ordered API from any source other than BRI/BioVectra, and that

Equally unjustified is the reference in your email - unsupported with any facts -- to "the misuse and badly manufactured API " Any such suggestion is wholly without basis and potentially damaging. Kindly cease and desist from making any such suggestions in the future.

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November 12, 2007 Page 3

there are no pending, unfilled orders for API placed by Keryx.

Since Panion has now – for the first time – professed that it is willing and able to serve as a source of API, Keryx will submit future purchase orders for API to Panion in accordance with Section 7.7 of the License Agreement. Keryx will expect from Panion binding commitments to provide API that is manufactured in accordance with the specifications developed by Keryx and BRI (which were provided to Panion) and pursuant to the delivery schedules set forth in such purchase orders.

Kindly confirm that the above undertaking suffices to cure any alleged breach in respect of Keryx's sourcing of API from third party source(s), or else state specifically what Panion contends is required to cure the alleged breach.

Reporting under Section 7.9 2.

In your email of November 5, you allege for the first time that Keryx is in "material breach" of Section 7.9 of the License Agreement for allegedly failing to provide progress reports. That allegation is likewise unjustified. As recently as August 24, 2007, Keryx provided to Panion a Regulatory, Non-clinical and Clinical Development Status Report dated August 23, 2007 and on September 11, 2007, Keryx provided to Panion a Chemistry, Manufacturing and Controls Status Report dated September 10, 2007. Accordingly, Keryx has provided to Panion within the last quarter - progress reports on the subjects specified in Section 7.9 of the License Agreement and is not in breach. Nevertheless, for the avoidance of doubt, Keryx will shortly provide a supplemental report updating Panion on further progress through September 30, 2007.

Royalty reports under Section 6.1 3.

Kervx hereby advises that no First Commercial Sale has been made under the License Agreement. Accordingly, no royalty reports are yet due under Section 6.1 of the License Agreement.

Patent prosecution, including Japanese Patent Application 4.

Panion has failed to comply with Section 8.1.1 of the License Agreement, which expressly requires that Panion "shall use reasonable efforts to prosecute the patent applications" and "shall regularly consult with Licensee and shall keep Licensee advised of the status of all patent applications and patents relating to the Patent Rights . . ." Despite numerous requests by Keryx for a docket report on the Patent Rights, Panion repeatedly refused to respond to Keryx or to provide a docket. Even when Keryx requested a docket report for Japan only in connection with the sublicense agreement, Panion refused to do so until Keryx agreed to pay Panion's patent counsel directly, which Keryx did on October 1, 2007. Panion has neither provided the requested docket reports, nor provided any explanation for its failure to comply with these

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November 12, 2007 Page 4

requests. Panion's failure to keep Keryx apprised of developments with respect to the patent applications is a serious breach of its obligations under the License Agreement. Please advise when Panion will produce a complete docket report for the Patent Rights.

Even more serious is Panion's behavior regarding prosecution of Dr. Hsu's Japanese Patent Application, which is of critical importance both to Keryx and to Japan Tobacco, Keryx's sublicensee. Faced with the second rejection of the Japanese patent application by the Japanese Patent Office. Panion initially permitted Japan Tobacco's patent counsel to collaborate with Panion's Japanese patent counsel in evaluating the pending Notice of Office Action issued by the Japanese Patent Office and determining how to prepare a response. As reported to Keryx by Japan Tobacco, it was agreed at the meeting between Panion's and Japan Tobacco's patent counsel that a 3-month extension should be sought so that Japan Tobacco could undertake a comprehensive search to identify and analyze published articles that support the patentability of the claimed subject matter. In your email dated October 24, 2007, Panion agreed to request a 3month extension. But the very next day, October 25, Panion sent a further email in which it refused to seek the extension "based on the unresolved issues between Keryx and Panion." This refusal is a blatant attempt to hold hostage the prosecution of Dr. Hsu's patent application and to use it for leverage against Keryx. Moreover, Panion has now refused to permit its Japanese patent counsel to interact with Japan Tobacco's patent counsel. These actions by Panion violate Panion's obligation to consult in good faith with Keryx as well as the obligation of good faith and fair dealing that is implied in all contracts, including the License Agreement. This refusal also violates Panion's fiduciary obligations to Dr. Hsu, whose valuable patent rights in Japan are being jeopardized by Panion in a bad-faith attempt to secure leverage over Keryx - conduct that would give Dr. Hsu a cause of action against Panion.

As set forth in the email to you from Beth Levine, dated November 6, 2007, Keryx has offered to pay the incremental cost of requesting a three-month extension for responding to the Notice of Office Action, so that Japan Tobacco can perform a literature search in support of the pending claims and analyze the results of that search. Accordingly, Keryx requests that Panion promptly confirm that it will seek a 3-month extension, in accordance with its undertaking of October 24, 2007 and consistent with its duty to Keryx and to Dr. Hsu.

5. Discussions with Dr. and Mrs. Hsu

There is absolutely no foundation for Panion's assertion that Keryx has "tortuously interfered" with the relationship between Panion and Dr. Hsu. On the contrary, as explained in the email to you from Beth Levine, dated October 26, 2007, Mrs. Hsu approached Keryx concerning an alleged prior assignment of patent rights by Dr. Hsu to Mrs. Hsu that purported to undermine the exclusive license granted by Dr. Hsu to Panion, from which Keryx's own rights as sublicensee flow. Far from interfering with the license agreement between Panion and Dr. Hsu, Keryx sought – and has succeeded – in persuading the Hsus to desist from challenging the exclusive license that Dr. Hsu granted to Panion.

Fried, Frank, Harris, Shriver & Jacobson LLP

Albert Wai-Kit Chan, Ph.D., Esq.

November 12, 2007 Page 5

We are unable to discern from your email what provisions of the License Agreement Panion is relying on for its demand that Keryx refrain from further communications with the Hsus and that Keryx provide to Panion records of such communications. Keryx gives no undertaking in that regard. If Panion persists in these demands, please identify with specificity the provisions of the License Agreement upon which such demands are based.

6. Two new indication patent applications

Keryx is still evaluating the two new indication patent applications for which Panion first provided summary information on September 26, 2007, and will respond as promptly as possible, and in any event before expiry of the Right of First Negotiation on December 25, 2007. In this regard, Keryx is still awaiting the revised sets of claims which Panion agreed to provide and which would be helpful to Keryx in evaluating what aspects of the claimed subject matter extend to new indications as distinct from subject matter already within the field of the existing License Agreement. Kindly advise when Panion will provide Keryx with the revised sets of claims as previously agreed.

7. Panion's letters to BRI and BioVectra

Keryx rejects any allegation that BioVectra's manufacturing activities or BRI's testing activities on behalf of Keryx were an improper use of Panion's technology. On the contrary, Section 3.1 of the License Agreement specifically authorizes and grants to Keryx the right to "develop, have developed, make [and] have made . . . the Product in the Territory, under the Licensor Know-How and Patent Rights . . ." In Section 1.13 of the License Agreement, "Licensor Know-How" is specifically defined as including "discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise" which are "necessary or useful to Licensee in connection with the development [or] manufacture . . . of a Product . . ."

In other words, Keryx has bought and paid for the right to use Panion-owned technology? in order to have API made for the purpose of developing or manufacturing the licensed Product. Moreover, Panion separately requested and authorized BRI to work with Keryx and BioVectra in the API manufacturing and development activities that were contracted and paid for by Keryx. Panion's recent communications with Keryx's contractors charging that the contractual activity conducted for Keryx improperly uses Panion-owned technology is false and without foundation, and constitutes a tortious interference by Panion with the relationship between Keryx and its contractors. Moreover, Panion has no right to obtain from those contractors confidential documents containing trade secrets owned by Keryx, and in attempting to do so Panion has attempted to misappropriate Keryx's trade secrets. Keryx requires Panion to cease and desist immediately from the foregoing improper conduct, and demands that Panion issue written retractions of the allegations and demands that Panion made to BRI and BioVectra (with copies

Case 1:07-cv-10376-CSH Document 14-11 Filed 11/26/2007 Page 7 of 7 Fried, Frank, Harris, Shriver & Jacobson LLP

Albert Wai-Kit Chan, Ph.D., Esq.

November 12, 2007 Page 6

to Keryx).

This letter is sent without prejudice to Keryx's contractual and other legal rights and defenses and without waiver thereof, all of which are hereby expressly preserved.

We look forward to your prompt response concerning the foregoing matters.

Yours truly,

180

Stephen S. Rabinowitz

Cc: Jack W. Chung, Esq. Beth Levine, Esq.

EXHIBIT 3

One New York Plaza New York, New York 10004-1980 Tel: +1.212.859.8000

Fax: +1.212.859.4000 www.friedfrank.com



Direct Line: 212.859.8579

Fax: 212.859.4000

Gregg.Weiner@friedfrank.com

November 16, 2007

Via Email and Federal Express

Jack W. Chung P.C. 401 Broadway, Suite 2009 New York, NY 10013

Albert Wai-Kit Chan, Ph.D., Esq. Law Offices of Albert Wai-Kit Chan PLLC World Plaza, Suite 604 141-07 20th Avenue Whitestone, NY 11357

Re: Keryx Biopharmaceuticals Inc. v. Panion & BF Biotech, Inc. (07 CV 10376)

Dear Messrs. Chung and Kit-Chan:

This office represents Keryx Biopharmaceuticals Inc. ("Keryx").

Attached is a copy of the Summons and Complaint filed this morning on behalf of our client against your client Panion & BF Biotech, Inc. This is to advise you that on Monday, November 19, 2007, at 12:00 noon, I will be filing in the Orders and Appeals Clerk's Office of the United States District Court for the Southern District of New York, 500 Pearl Street, New York, New York, an application for an Order to Show Cause seeking an early hearing on Keryx's prayer for preliminary injunctive relief and granting expedited proceedings, including expedited discovery.

After filing the application I will proceed to the chambers of Judge Haight or the Part I Judge to seek the requested relief.

Should you choose to appear at such hearing, you should meet me in the Order and Appeals Clerk's Office at 12:00 noon on Monday, November 19.

r Case 1:07-cv-10376-CSH Fried, Frank, Harris, Shriver & Jacobson LLP

Jack W. Chung P.C. Albert Wai-Kit Chan, Ph.D., Esq. November 16, 2007 Page 2

Finally, you should inform your client of its obligation to preserve and retain all documents that might potentially be relevant to this litigation. This includes

- all documents relating to the License Agreement;
- all documents relating to Keryx;
- all documents relating to Biopharmaceutical Research Inc. ("BRI");
- all documents relating to BioVectra DCL ("BioVectra");
- all documents relating to Japan Tobacco Inc. ("Japan Tobacco");
- all documents relating to Torii Pharmaceutical Co., Ltd. ("Torii");
- all documents relating to PharmPro Processing Services of Fluid Air Inc. ("PharmPro");
 and
- all documents relating to the licensed product, ferric citrate.

Under the Federal Rules, the term "documents" is broadly defined to include all means of preserving information, including electronic documents and hard-copy documents, drafts, memos, spreadsheets, handwritten notes (formal or informal), notebooks, computer disks (including CDs or DVDs), e-mails, calendars, faxes, and every other way of storing or presenting information, including PDAs. This is a continuous request, and covers any documents that are created after the date of this Letter.

Panion is obligated to take affirmative steps to ensure that the relevant documents are preserved and not discarded even as part of normal document control and retention procedures. There could be serious legal consequences if relevant documents are not preserved and retained.

Very truly yours,

Gregg L. Weiner

GLW:jb

559566

Document 14-12

Filed 11/26/2007

Page 4 of 19

AO 440 (Rev. 8/01) Summons in a Civil Action

UNITED STATES DISTRICT COURT

Southern

District of

New York

KERYX BIOPHARMACEUTICALS, INC.

SUMMONS IN A CIVIL ACTION

٧.

PANION & BF BIOTECH, INC.

OPT 10376

TO: (Name and address of Defendant)

PANION & BF BIOTECH, INC. 16F NO. 3, YUANQU STREET NANGANG DISTRICT TAIPEI, TAIWAN REPUBLIC OF CHINA

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

GREGG L. WEINER FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP ONE NEW YORK PLAZA NEW YORK, NEW YORK 10004-1980

in answer to the complaint which is served on you with this summons, within twenty (20) days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

J. MICHAEL McMAHON

NOV 1 6 2007

CLERK

DATE

By) DEPUTY CLECK

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07 CV 10376

Gregg L. Weiner
Stephen S. Rabinowitz
Fried, Frank, Harris, Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004-1980
(212) 859-8000
Attorneys for Plaintiff

UNITED STATES DISTRICT CO FOR THE SOUTHERN DISTRIC	V	الناز تهوه	
KERYX BIOPHARMACEUTICA	: \	18 LOW 1 B LOW WIT.	
	;	U.S.CASHIERS	
- against -		:	COMPLAINT
PANION & BF BIOTECH, INC.,	·	:	
	Defendant.	:	
		A	

Plaintiff Keryx Pharmaceuticals, Inc. ("Keryx"), by its attorneys, for its Complaint in this action, alleges as follows:

NATURE OF ACTION

1. This is an action for declaratory and injunctive relief and damages arising from the threatened termination of a license agreement under which defendant Panion & BF Biotech, Inc. ("Panion") granted Keryx exclusive rights to develop and commercialize a licensed pharmaceutical product for treatment of kidney disease.

Panion's asserted basis for terminating the license agreement is incorrect. Moreover, in conjunction with its improper termination threats, Panion has breached the license agreement by attempting to prevent Keryx from developing the licensed product and has tortiously interfered with Keryx's ongoing contractual relations with third parties

who are assisting Keryx in developing the licensed product. Panion's actions threaten to cause Keryx irreparable harm.

PARTIES AND JURISDICTION

- 2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with its principal place of business at 750 Lexington Ave., 20th Floor, New York, NY 10022.
- 3. Upon information and belief, Panion is a corporation organized and existing under the laws of Taiwan, having an office in Queens County, New York and its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.
- 4. This action arises under the common law of the State of New York and the Declaratory Judgments Act, 28 U.S.C. §§ 2201 et seq.
- 5. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(a). The parties are of diverse citizenship, and the amount in controversy exceeds the sum or value of seventy-five thousand dollars (\$75,000), exclusive of interest and costs.
 - 6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a).

BACKGROUND

7. Keryx is a pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious and life-threatening diseases, including diabetes, cancer, and renal (kidney) disease.

The License Agreement

- 8. Panion is the owner or exclusive licensee of certain patents and patent applications, including U.S. Patent No. 5,7753,706, issued May 19, 1998, for an invention entitled "Methods For Treating Renal Failure" (the "Hsu Patent"). The Hsu Patent describes and claims a method of controlling phosphate retention in patients suffering from elevated phosphate levels by administering a therapeutically effective amount of ferric citrate. Phosphate retention leading to elevated phosphate levels is a common and serious complication of advanced renal disease.
- 9. Keryx and Panion are parties to a license agreement, dated November 7, 2005 (the "License Agreement") whereby Panion (Licensor) granted to Keryx (Licensee) an exclusive license under the Hsu Patent, its corresponding foreign counterparts, and other Panion-owned or Panion-controlled patents and patent applications, to develop and commercialize ferric citrate and pharmaceutical products containing ferric citrate as an active ingredient (collectively, the "Product") throughout most of the world, including but not limited to the United States, Canada and Japan, for treatment of renal disease.
 - 10. Section 3.1 of the License Agreement provides:

Grant. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive license, in the Territory, with the right to sublicense, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product in the Territory under the Licensor Know-How, and the Patent Rights for all Indications in the Field.

11. As defined in Section 1.13 of the License Agreement, the term "Licensor Know-How" includes:

discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise, in each case, which as of the Effective Date and during the term of this Agreement are necessary or useful to Licensee in connection with the development, registration, manufacture, marketing, use or sale of a Product.

12. Section 7.7 of the Agreement provides, in part:

Both parties agree to work in good faith to fully collaborate to review and administer the manufacturing program for the Compound and to resolve any technical issues both immediately after the Effective Date and at least annually thereafter during the Exclusive Supply Period as defined below.

For the period commencing on the Effective Date and continuing for three (3) years following Registration in the United States (the "Exclusive Supply Period"), Licensee (and its Sublicensees) shall obtain their supply of the Clinical Supplies and of the Compound exclusively from Licensor. In consideration for such supply, Licensee shall provide compensation to Licensor at fifteen percent (15%) over Licensor's manufacturing and procurement cost. Notwithstanding the preceding two sentences, decisions and actions related to pharmaceutical development and manufacturing of the Clinical Supplies are subject to joint review and approval. During the Exclusive Supply Period, Licensee shall be entitled to engage an alternative supplier of Clinical Supplies of the Compound provided that (i) Licensee has demonstrated to Licensor that the Clinical Supplies or the Compound subject to this Section 7.7(b) can be made available to Licensee by an alternative third-party supplier at a price that is more than 25% below what Licensor charges Licensee in accordance with this Section 7.7(b); and (ii) Licensor within sixty (60) days thereafter fails to meet the price offered by such alternative supplier.

13. After entering into the License Agreement, Keryx and Panion began discussing the development of improved processes and specifications for manufacturing, at commercially reasonable cost, Active Pharmaceutical Ingredient

("API") containing pharmaceutical-grade ferric citrate suitable for treatment of human patients suffering from advanced renal disease. A supply of API is indispensable for performing the preclinical testing and clinical trials that are needed to obtain regulatory approval from the Federal Food and Drug Administration ("FDA") and its foreign counterparts to commercialize pharmaceutical agents containing ferric citrate.

Panion's Acquiescence in Kervx's Orders of API

14. On July 26, 2006, Keryx sent an email to the President of Panion detailing an urgent need for 100kg of API to be sent under the conditions of the contract to begin critical path toxicology studies. Instead of responding in an urgent manner in spite of Keryx's repeated requests to supply quantities as low as 5 kg immediately so it could begin those studies, Panion introduced Keryx to its previous contractor, BRI Biopharmaceutical Research Inc. ("BRI"), located in Vancouver, Canada, for the purposes of organizing supply but then declined to participate in any planning, saying that it just wanted to be kept informed. Keryx kept Panion informed of its development program by emails and progress reports, and invited Panion to attend meetings with BRI, which Panion declined on the grounds that "Panion is a small company with limited budget and resources."

- Page 11 of 19
- 15. BRI introduced Keryx to BioVectra DCL ("BioVectra"), located in Prince Edward Island, Canada, and through BioVectra to a subcontractor, the PharmPro Services division of Fluid Air, Inc., ("PharmPro"), located in Aurora, IL. Working with BRI, BioVectra and PharmPro, Keryx has incurred significant expenditures and devoted substantial corporate resources to the development of specifications and manufacturing processes for API. Not until September 1, 2006, did Panion respond definitively that it had "checked the inventory and found out we don't have any quantity in stock."
- 16. On September 5, 2006, Keryx placed a purchase order with BioVectra for the manufacture of 400 kg of API, in 3 lots, under a quotation that Panion had requested Keryx to obtain and that had been emailed to Keryx, with a copy to Panion, on August 24, 2006. Despite its awareness of the impending order for production, Panion did not object to Keryx or offer to participate in any active way.
- 17. On September 11, 2006, Keryx emailed Panion offering to increase its order for API to cover any needs that Panion might have. Without objecting to Keryx's order or offering to take over the work of coordinating the production, Panion responded that it had sufficient API for its own purposes. After receiving Panion's response, Keryx ordered a fourth batch of API from BioVectra. Panion continued to be copied on emails periodically over the coming month and a half until production began, and then over the subsequent two months on discussions of changes in specifications and controls. At no time did it raise any objection to the fact that Keryx and BRI were working together to coordinate the production or offer

to participate in any active way. The four batches of API have been manufactured and title has passed to Keryx.

- 18. In February, 2007, after the production and formal release of the product for use, Keryx and Panion exchanged correspondence and finally a formal letter of understanding regarding regulatory reporting of the results of the production. At no time did Panion object to the fact that Keryx had organized the production and paid for it directly.
- has contracted and borne the entire expense for additional development work by BRI, BioVectra and PharmPro aimed at improving the efficiency (i.e., lowering the cost and increasing the yield) of producing API and assuring its stability. The continuing development work will not result in Keryx being supplied with additional API over and above the four lots that Keryx previously ordered. Keryx has now made a substantial investment in lowering the cost of manufacturing which is a critical component of commercializing ferric citrate (i.e., the development of a commercially feasible, cost-effective process for manufacturing pharmaceutically pure API suitable for clinical trials and commercial sale).

The Japanese Sublicense

20. On September 26, 2007 Keryx concluded an agreement (the "Sublicense") with Japan Tobacco, Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii") by which Keryx granted to JT and Torii an exclusive sublicense under the License Agreement to develop and commercialize ferric citrate in Japan, in exchange for an initial licensing fee of \$12 million plus future milestone and royalty payments.

Page 12 of 19

Under the License Agreement, Panion is not entitled to share in the initial licensing fee or milestone payments.

Panion's Threatened Termination and Interference With Licensed Activities

- 21. On October 31, 2007 Panion's counsel sent Keryx an email contending that Keryx's purchases of API, under contracts entered into a year earlier, constituted a "material breach" of the Licensing Agreement that "has not been cured for more than ninety days" and threatening to take "appropriate actions to nullify the agreement." The License Agreement gives Panion (Licensor) a right to terminate for cause "upon or after the breach of any material provision . . . by Licensee if such breach is not cured within ninety (90) days after Licensor gives Licensee written notice thereof" No prior written notice of any alleged breach of the Licensing Agreement had been given to Keryx before October 31, 2007.
- 22. On or about November 8 and 9, 2007, Panion accused BRI, BioVectra and PharmPro of making improper use of Panion-owned technology and threatened to commence legal action against them unless they discontinued their contractual activities for Keryx.
- 23. On November 12, 2007, Keryx's counsel wrote to Panion's counsel pointing out that Panion had acquiesced in Keryx's prior purchases of API, stating that Keryx had no pending unfilled orders for supply of API, agreeing that Keryx would submit future purchase orders for supply of API to Panion in accordance with Section 7.7 of the License Agreement, and demanding that Panion cease and desist from threatening Keryx's contractors and that Panion retract the demands and allegations it had issued to them.

- 24. On November 13, 14 and 15, 2007, Panion's counsel again contacted PharmPro, BRI and BioVectra, respectively, again threatening that Panion would commence legal action unless they discontinued their contractual activities for Keryx.
- On November 15, 2007, Panion filed a Summons with Notice in 25. Oueens County, New York asserting claims against BRI.

FIRST CAUSE OF ACTION (Breach of contract)

- Paragraphs 1-25, above, are realleged and incorporated by reference as 26. if set forth in full.
- Under the License Agreement, Panion has authorized Keryx to use 27. Panion-owned technology to "develop [and] have developed" API containing pharmaceutical-grade ferric citrate.
- The threats and demands issued by Panion against BRI, BioVectra and 28. PharmPro constitute a breach of Keryx's rights under the License Agreement to develop API.
- Panion's conduct, unless enjoined, will cause Keryx irreparable harm 29. for which it has no adequate remedy at law.

SECOND CAUSE OF ACTION (Tortious interference with contractual relations)

- Paragraphs 1-29, above, are realleged and incorporated by reference as 30. if set forth in full.
- By demanding that BRI, BioVectra and PharmPro cease the 31. development activities they are performing under contract to Keryx, Panion has tortiously interfered with the ongoing contractual relationship between Keryx and

BRI, BioVectra and PharmPro. Panion has made these demands knowing that they are contrary to the rights granted Keryx under the License Agreement and for the purpose of harming Keryx.

- 32. Unless enjoined, Panion will continue to interfere with Keryx's contracts with BRI, BioVectra and PharmPro.
- 33. Panion's conduct threatens Keryx with irreparable harm for which it has no adequate remedy at law.

THIRD CAUSE OF ACTION

(Declaratory judgment that Keryx has not breached the License Agreement)

- 34. Paragraphs 1-33, above, are realleged and incorporated by reference as if set forth in full.
- 35. Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro did not breach the License Agreement, among other reasons, because Panion acquiesced in and consented to those purchases.
- 36. Panion is estopped from contending that Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro constitute a breach of the License Agreement.
- 37. Moreover, any alleged breach by virtue of Keryx's direct order for supply of four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro did not materially breach the License Agreement.
- 38. A ripe, justiciable controversy exists between Panion and Keryx concerning whether Keryx has breached the Agreement by purchasing four lots of API manufactured by BioVectra in conjunction with BRI and PharmPro.

FOURTH CAUSE OF ACTION (Anticipatory breach)

- 39. Paragraphs 1-38, above, are realleged and incorporated by reference as if set forth in full.
- 40. Section 12.3.1. of the License Agreement prohibits Panion from terminating the License Agreement for a material breach unless and until Keryx has failed to cure the breach within ninety (90) days after Panion has given Keryx written notice thereof.
- 41. In its initial notice dated October 31, 2007, Panion stated that Keryx's alleged material breach "has not been cured for more than ninety days" and threatened to take "actions to nullify th[e] agreement." Panion thereby breached the termination clause of the License Agreement by failing to give Keryx ninety days after notice to cure the alleged breach.
- 42. Panion is not entitled to terminate the License Agreement and its threat to do so breaches the express provisions thereof.
- 43. Panion's conduct threatens Keryx with irreparable harm for which it has no adequate remedy at law.

FIFTH CAUSE OF ACTION (Breach of contract)

- 44. Paragraphs 1-43, above, are realleged and incorporated by reference as if set forth in full.
 - 45. Section 8.1.1 of the License Agreement provides:

Licensor shall use reasonable efforts to prosecute the patent applications included in the Patent Rights... Licensor shall regularly consult with Licensee and shall keep Licensee advised of the status of all patent

applications and patents relating to the Patent Rights by providing Licensee with copies of such patent applications and patents and copies of all patent office correspondence relating thereto including any office actions received by Licensor and responses or other papers filed by Licensor. Licensor specifically agrees to provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Licensor any proposed response thereto. Licensor further agrees to provide Licensee with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult on all proposed responses to patent office correspondence relating to such patent applications and patents.

- 46. Keryx has repeatedly requested Panion to provide a comprehensive docket report on the Patent Rights licensed to Keryx under the License Agreement. Panion has neither provided the requested docket report, nor provided any explanation for its failure to comply with these requests.
- 47. On or about August 28, 2007, the Japanese Patent Office issued a Notice of Office Action concerning the Japanese counterpart of the Hsu Patent.
- 48. Panion initially permitted its Japanese patent counsel to collaborate with the patent counsel of Japan Tobacco, Keryx's sublicensee, in evaluating the Notice of Office Action and determining how to prepare a response.
- 49. On information and belief, it was agreed at the meeting between Panion's and Japan Tobacco's patent counsel that a 3-month extension should be sought so that Japan Tobacco could undertake a comprehensive search to identify and analyze published articles that support the patentability of the claimed subject matter.
- 50. On October 24, 2007, Panion's counsel notified Keryx that Panion would request a 3-month extension. The very next day, October 25, 2007, Panion's counsel sent Keryx a further email in which Panion refused to seek the extension

"based on the unresolved issues between Keryx and Panion." Panion also instructed its Japanese patent counsel to stop interacting with the patent counsel of Japan Tobacco.

- 51. Panion has breached the License Agreement by failing to consult in good faith with Keryx concerning prosecution of the licensed patent applications and by failing to keep Keryx informed of the status of the licensed patents and patent applications.
 - Panion's conduct has damaged Keryx.WHEREFORE, Keryx demands judgment as follows:
 - 1. Declaring that:
 - a) Keryx is not in breach of the License Agreement;
 - b) the alleged breach concerning orders for supply of API is not material;
 - c) Keryx has until January 30, 2008 to cure any alleged breach concerning orders for supply of API; and
 - any notice by Panion purporting to terminate the License
 Agreement is null and void;
 - 2. Preliminarily and permanently enjoining:
 - a) Panion from issuing a notice to terminate the License

 Agreement before Keryx's time to cure any alleged

 breach has expired; and

- b) Panion from taking any action to interfere with Keryx's rights under the License Agreement, including its right to contract with third parties to develop the Product;
- Directing Panion to pay damages to Keryx in an amount to be determined at trial, with interest thereon;
- 4. Awarding Keryx punitive damages on its claim for tortious interference;
- 5. Awarding Keryx its costs and disbursements (including expert and attorneys' fees incurred in this action); and
- 6. Awarding Keryx such other and further relief as the Court may deem just and proper.

Dated: New York, New York November 16, 2007

FRIED, FRANK, HARRIS, SHRIVER &

JACOBSON LLP

By:

Gregg L. Weiner

Stephen S. Rabinowitz (Members of the Firm)

One New York Plaza New York, NY 10004-1980 (212) 859-8000

Attorneys for Plaintiff Keryx Biopharmaceuticals, Inc. EXHIBIT 4

COUNTY OF QUEENS X	
PANION & BF BIOTECH, INC. Plaintiff,	INDEX NO.: 28535/07
vs.	SUMMONS WITH NOTICE
BRI BIOPHARMACEUTICAL RESEARCH, INC. Defendant,	Date Index No. purchased
X	' .
To the Person(s) Named as Defendant(s) above:	
PLEASE TAKE NOTICE THAT YOU ARE HER	EBY SUMMONED to appear
in this action by serving a notice of appearance on the pla	intiff at the address set below,
and to do so within 20 days after the service of this Sum	mons (not counting the day of
service itself), or within 30 days after service is complete i	f the summons is not delivered
personally to you within the State of New York.	
YOU ARE HEREBY NOTIFIED THAT should y	ou fail to answer or appear, a
	C.1. 1.311

judgment will be entered against you by default for the relief demanded below.

Date: Queens, New York November /5 , 2007

Attorney for Plaintiff

Jack W. Chung

World Plaza, Suite 604 141-07 20th Avenue

Whitestone, New York 11367

Phone: (718)799-1000

(718)357-8615 Fax:

BRI Biopharmaceutical Research, Inc. Defendant:

101-8898 Heather Street

Vancouver, British Columbia CANADA V6P358

Notice

The nature of this action is: breach of contract and others.

The relief sought is:

- (1) Court order to temporarily injunct defendant BRI to use Panion's technologies.
- (2) Court order to permanently injunct defendant BRI to use Panion's technologies.
- (3) Monetary damage in the amount of one million dollars (\$1,000,000.00) or in the amount to be determined at trial.
- (4) Court order requiring defendant to preserve and return all technologies and records to plaintiff Panion.
- (5) Court order requiring defendant to maintain Panion's technologies confidential and requiring defendant to provide a list of names to which the technologies have been revealed to by the defendant.

Should defendant fail to appear herein, judgment will be entered by default for the sum of one million dollars (\$1,000,000.00) with interests from the date of November 15, 2007 and the costs of this action.

Venue:

Plaintiff designates Queens County, State of New York as the place of trial. The basis of this designation is:

Plaintiff maintains office in Queens County, State of New York.

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BECEINED

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Case 1:07-cv-10376-CSH Docume	ent 14-13 Filed 11/26/2007 Page 4 of 4
SUPREME COURT OF THE STATE OF NEW Y	ORK X
PANION & BF BIOTECH, INC.	Index No.:
Plaintiff,	
-against-	
BRI BIOPHARMACEUTICALS RESEARCH, IN	IC.,
Defendant,	·X
·	
SUMMONS WI	TH NOTICE
World Plaza, 141-07 20 th Whitestone, New Tel: (718) 7 Fax: (718) 3 The undersigned attorney hereby certifies, pursuant to 2 papers and that to the best of my knowledge and belief NYCRR § 130-1.1(c).	Avenue 7 York 1/1357 99-1000 57-8615 22 NYCRR §130-1.1-a, that I have read the within they are not frivolous as that term is defined in 22
	Attorney Name: JACK CHUNG
Dated: Nevember 15, 2007	
OUEENS COUNTY CL	

EXHIBIT C

SUPREME COURT COUNTY OF QUE	OF THE STATE OF NE	EW YORKX
PANION & BF BIO	TECH, INC. Plaintiff,	INDEX NO.: 28698 /0:
	vs.	SUMMONS WITH NOTICE
BioVectra DCL,	Defendant,	Date Index No. purchased November 19, 2007
		x
To the Person(s) Na	med as Defendant(s) abov	ve:
PLEASE TA	KE NOTICE THAT YO	OU ARE HEREBY SUMMONED to appear
in this action by serv	ving a notice of appearar	nce on the plaintiff at the address set below,
and to do so within	20 days after the service	e of this Summons (not counting the day of
service itself), or wit	thin 30 days after service	is complete if the summons is not delivered
personally to you wi	thin the State of New Yo	ork.
YOU ARE I	HEREBY NOTIFIED TH	HAT should you fail to answer or appear, a
judgment will be ent	ered against you by defar	ult for the relief demanded below.
Date: Queens, New November 19		
. 3 6	•	Attorney for Plaintiff Jack W. Chung
Defendant: 36.		Law Offices of Jack W. Chung P.C. 401 Broadway, Suite 2009
50 -		New York, NY 10013 Phone: (212)334-7118
		Fax: (212)334-6408
	anten DOY	E-mail: jackchunglaw@gmail.com
Jeiengant: BioV	ectra DCL cCarville Street	•
	ottetown, Prince Edward	l Island
	ADA C1E 2A6	·

Notice

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technology, trade secrets and others.

The relief sought is:

- (1) Court order to temporarily injunct defendant BioVectra DCL to use Panion's technologies.
- (2) Court order to permanently injunct defendant BioVectra DCL to use Panion's technologies.
- (3) Monetary damage in the amount of one million dollars (\$1,000,000.00) or in the amount to be determined at trial.
- (4) Court order requiring defendant to preserve and return all technologies and records to plaintiff Panion.
- (5) Court order requiring defendant to maintain Panion's technologies confidential and requiring defendant to provide a list of names to which the technologies have been revealed to by the defendant.

Should defendant fail to appear herein, judgment will be entered by default for the relief sought and the sum of one million dollars (\$1,000,000.00) with interests from the date of November 19, 2007 and the costs of this action.

Venue:

Plaintiff designates Queens County, State of New York as the place of trial. The basis of this designation is:

Plaintiff maintains office in Queens County, State of New York.

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